

USP 800 Provider



What is USP <800>?

- The United States Pharmacopeia (USP) is a nonprofit organization that sets standards for quality and safety of medications.
- Chapter <800> specifically outlines how healthcare organizations need to handle hazardous drugs (HDs) to **reduce unintentional exposure**.
 - The standards apply to **all** personnel who work in healthcare organizations
- **These standards are enforceable by The Joint Commission and CMS.**



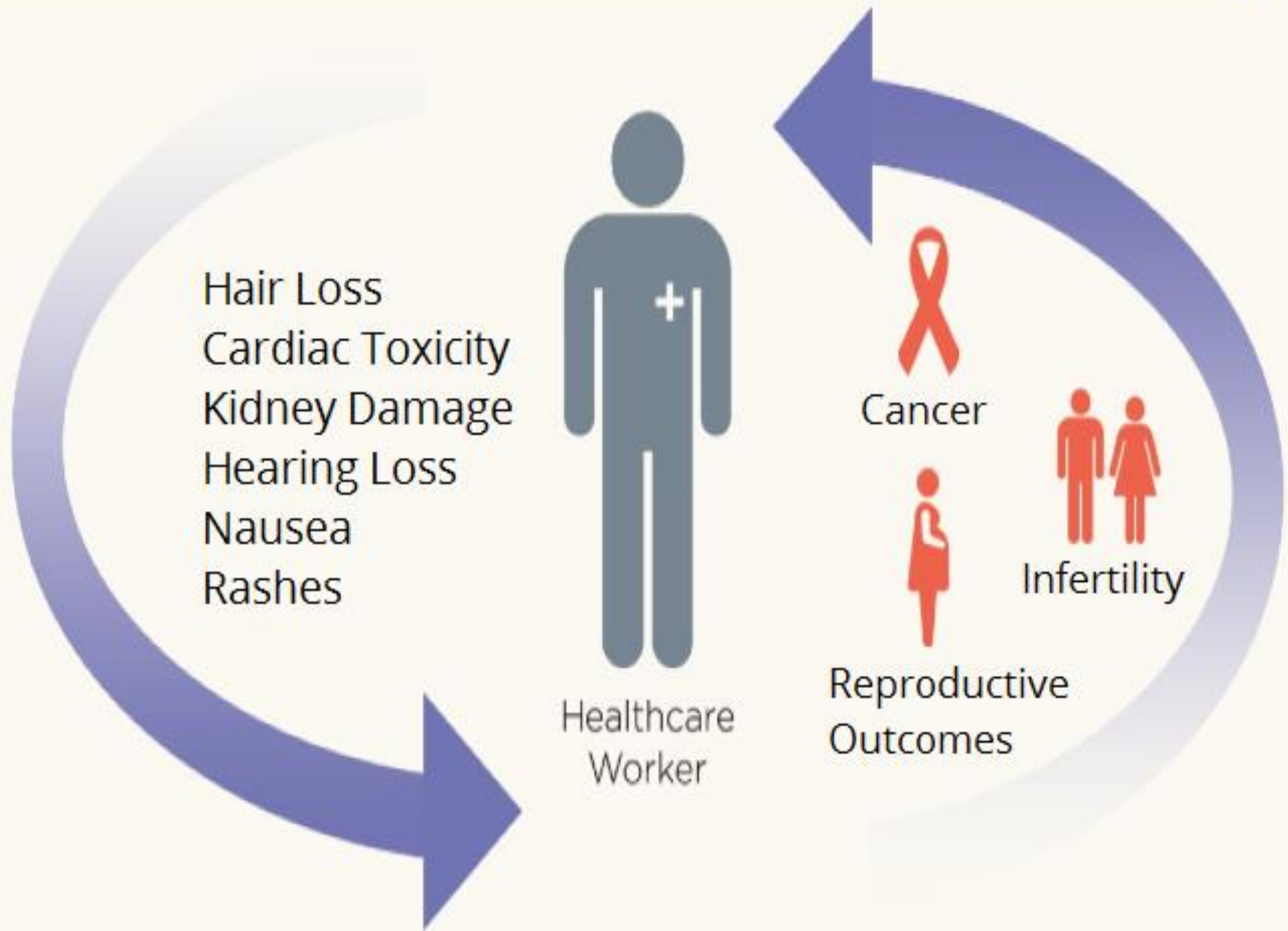
What are Hazardous Drugs?

Hazardous Drugs (HD) are defined by NIOSH (National Institute for Occupational Safety and Health) as having one or more of the following characteristics:

- Carcinogenicity (Risk for causing cancer)
- Teratogenicity (Risk for causing birth defects)
- Reproductive toxicity for both males and females (Risk for difficulty getting pregnant or staying pregnant)
- Organ toxicity at low doses
- Genotoxicity (Risk for causing genetic mutations)

WHAT ARE THE POTENTIAL RISKS?

Acute³ and long term^{4,5} effects



Why is this important?

The Focus is
on Healthcare
Worker
Safety!



How can exposure occur?

- Exposure can occur when hazardous drugs are inhaled, touched, injected or ingested OR if body fluids are splashed or spilled.
- Contamination could be on:
 - Packages containing hazardous drugs
 - The outside of prepared medications
 - Counters or tables
 - Any number of other containers or surfaces



How can exposure occur?



- Every aspect of handling hazardous drugs may result in exposure if proper precautions are not taken

Exposure Routes

- Absorption through skin and/or mucous membranes
 - Includes coming in contact with hazardous drug OR body fluids
- Inhalation if drugs or body fluids spray into the air
- Injection through a needle stick containing HD or blood
- Ingestion through eating contaminated food or touching contaminated hands to skin or mucous membranes



If I don't work in a patient care area, why do I need to know about this?

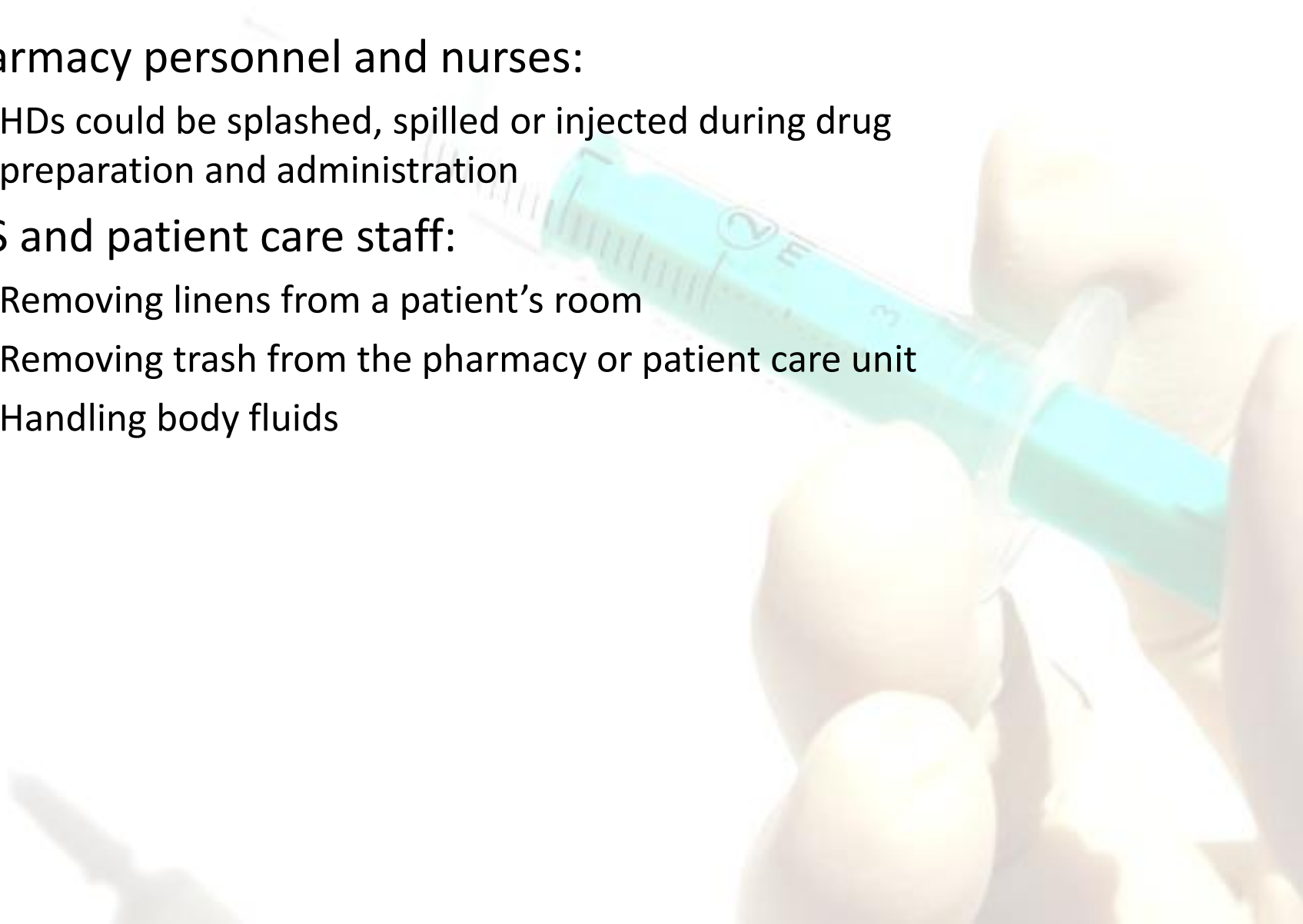


There is a risk for being exposed outside of patient care areas. The following are all examples of potential exposures:

1. A patient who received hazardous drugs is in the cafeteria for lunch and throws up
2. A patient is in the elevator and their IV tubing containing hazardous drug comes apart and spills
3. A box containing hazardous drug starts leaking as it is transported through the hospital

More exposure examples for staff in patient care areas

- Pharmacy personnel and nurses:
 - HDs could be splashed, spilled or injected during drug preparation and administration
- EVS and patient care staff:
 - Removing linens from a patient's room
 - Removing trash from the pharmacy or patient care unit
 - Handling body fluids



How do I protect myself against exposure?



1. Minimize the risk for exposure by adhering to policies and Standard Operating Procedures (SOPs)
2. Utilize Personal Protective Equipment (PPE) when indicated
3. Utilize other safety devices available in the pharmacy and to nursing when administering medications

Is it Hazardous?

- If you encounter some type of spill, consider it hazardous until otherwise identified
- If you have been exposed, call Employee Health (during business hours) and the nursing House Supervisor (after hours) for further direction.
 - More details on exposure can be found in the HD SOP
- Complete an [Eye on Safety](#) and notify your supervisor



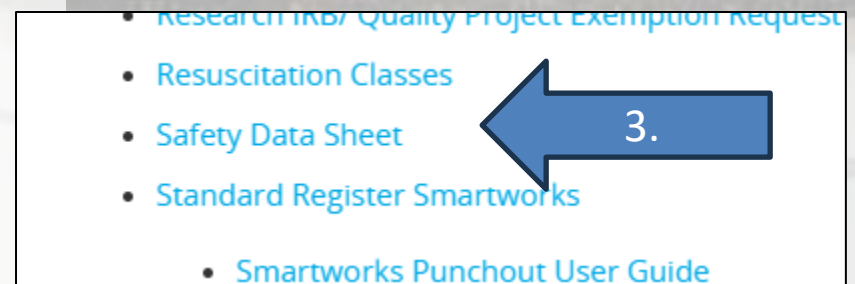
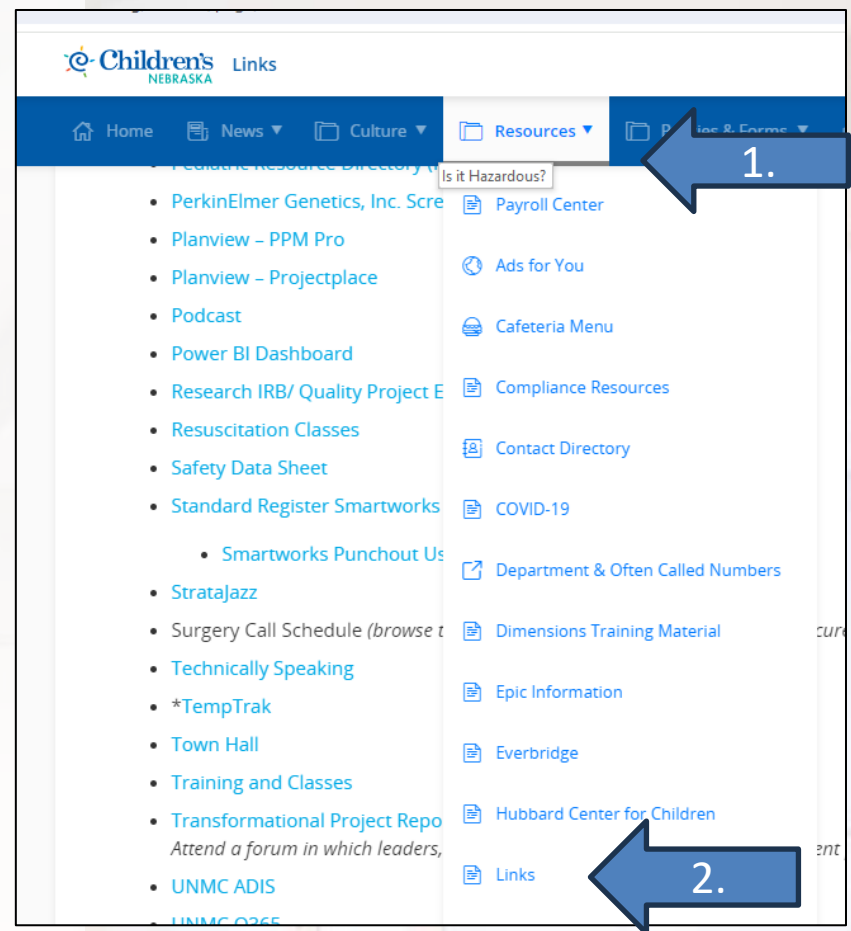
Resources

- **PolicyStat**

- Hazardous Drug Handling Policy: includes a list of hazardous drugs
- Administering, Handling & Disposal of Hazardous Drugs Policy: Includes more detail on patient care related to hazardous drugs

- Link to Safety Data Sheets (SDS) is on the homepage under “Links”

- All hazardous drugs have a SDS that is helpful if there is a spill or exposure



Basic HD Spill Control



- All personnel who might be required to clean up a spill must receive proper training in spill management and the use of personal protective equipment (PPE) and N95 masks.

Basic HD Spill Control

Those staff that have not been trained in hazardous drug spill clean up should: **SWIM**

- **S**top the Spread. Cover the spill if possible
- **W**arn others and call for assistance
 - Call 402-955-8999 to notify the Safety Officer for direction and coordination of the spill cleanup.
 - Notify the House Supervisor of the location of the spill
- **I**solate the area.
- **M**itigate risk and minimize exposure by donning full PPE and keeping others away

If I encounter a spill, what should I do?

- Call the call center at x8999 and follow “**SWIM**”
- Wipe it up
- Ignore it and keep walking
- Call the Ghostbusters

Knowledge Check

If I have a question about USP<800>, what are my appropriate resources?

- a. PolicyStat
- b. Google search
- c. My supervisor
- d. HD Resource Page on Intranet
- e. A, C, and D

Knowledge Check

What do I do if I think I was exposed to a Hazardous Drug?

- a. Call Employee Health (if during business hours)
- b. Contact the nursing House Supervisor (if after hours)
- c. Call the IT Helpdesk
- d. Ignore it
- e. A and B

Knowledge Check



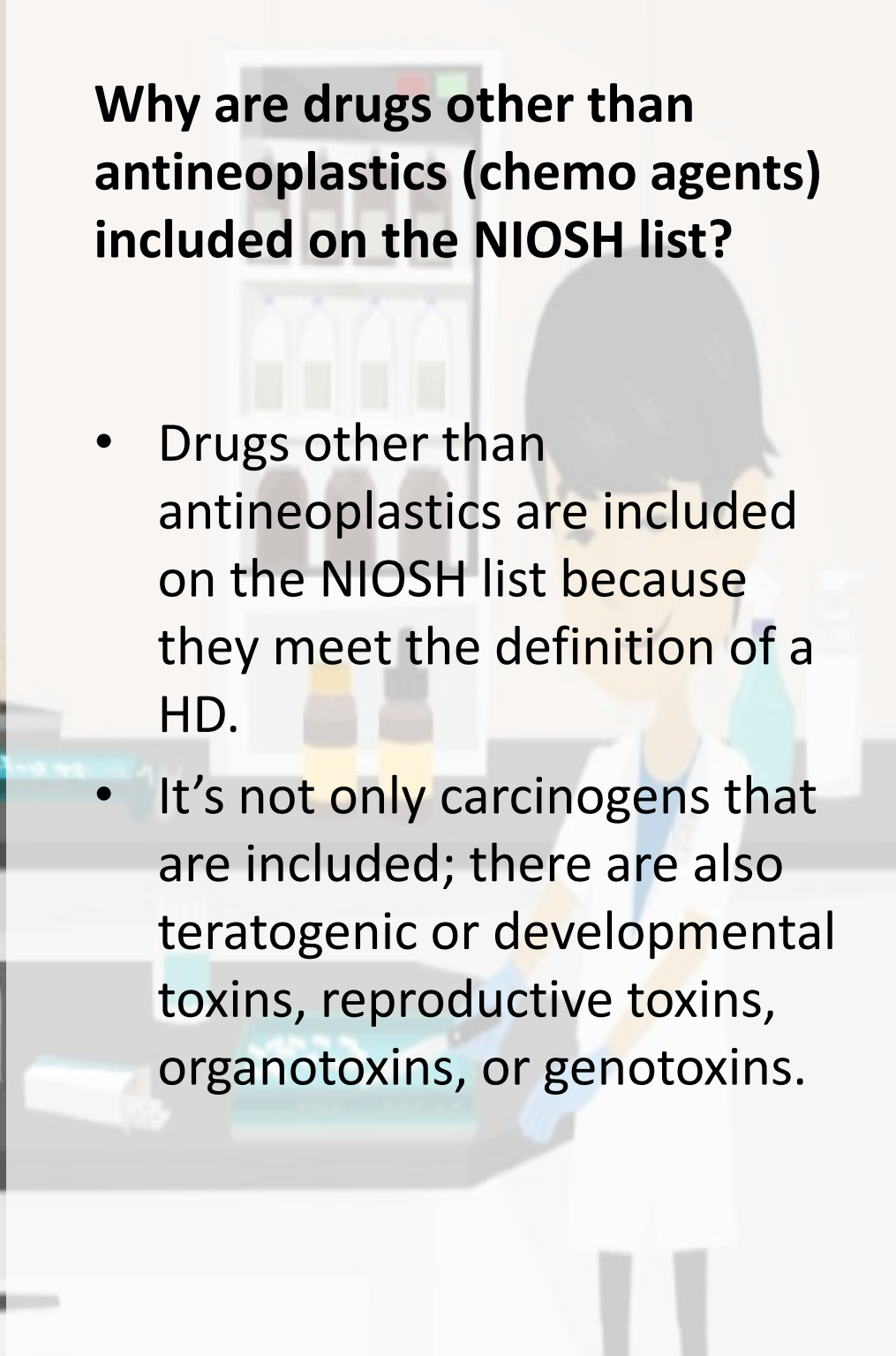
USP <800>

This next set of USP<800> related education will review in more detail information that is pertinent for Providers

HD List

Why are drugs other than antineoplastics (chemo agents) included on the NIOSH list?

- Drugs other than antineoplastics are included on the NIOSH list because they meet the definition of a HD.
- It's not only carcinogens that are included; there are also teratogenic or developmental toxins, reproductive toxins, organotoxins, or genotoxins.



HD List

What do the different risk categories mean?

- HDs are grouped in the different categories based on drug make-up and the amount of manipulation required.
- You may see different routes of the same drug in different categories due to amount of manipulation.
- PPE needs also vary based on the category.

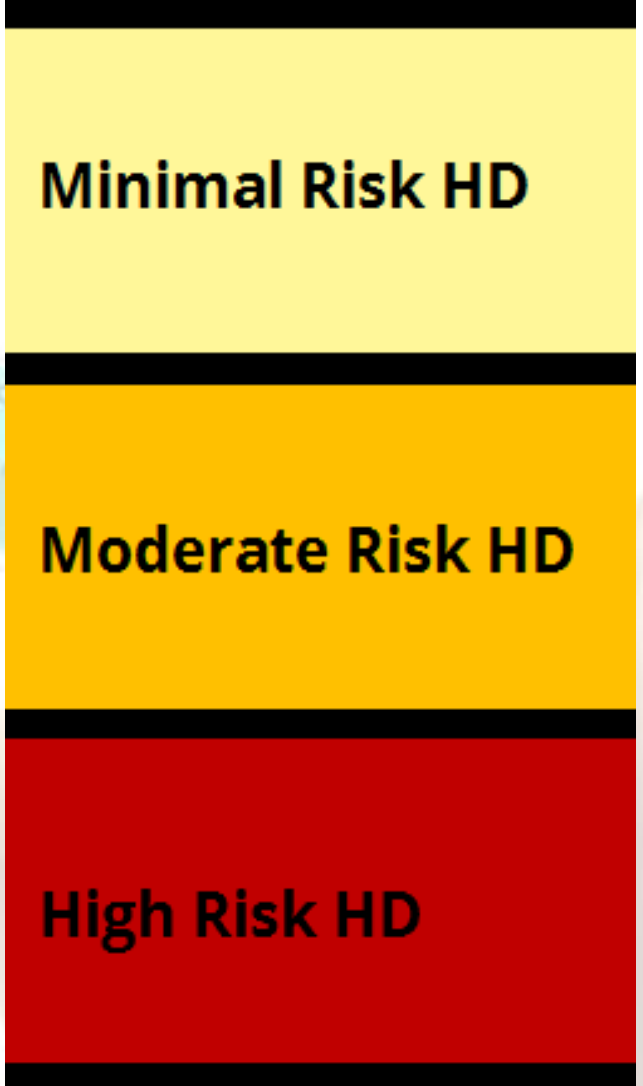
Minimal Risk HD

Moderate Risk HD

High Risk HD

HD Classifications

- Each Hazardous drug in the organization has been classified into 3 categories
- Each risk category is color coded
- Each HD will have a risk indication in the Medication Administration Record (MAR) and on the drug label
- Each HD will be delivered from pharmacy in an HD bag



Minimal Risk HD

Moderate Risk HD

High Risk HD

What Medications Are Included?

Minimal Risk HD

- Primarily medications which NIOSH identify as having potential reproductive risks
- Examples: Topiramate PO, Clonazepam PO, Fluconazole PO & Warfarin PO

Moderate Risk HD

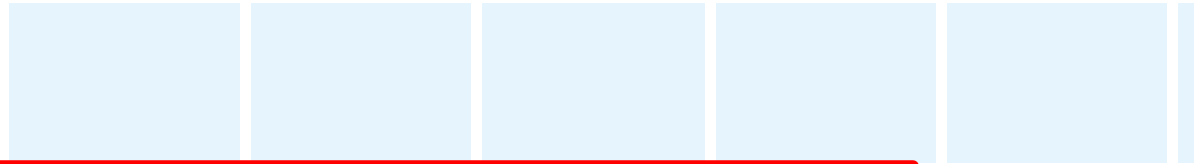
- Oral chemo, immunosuppressants
- Other oral medications on the NIOSH list
- Examples: PO Cyclosporine, PO Azathioprine, Mercaptopurine oral solution, Methotrexate tablet

High Risk HD

- Injectable chemotherapies
- Other injectable medications on the NIOSH list
- Examples: IV Methotrexate, IV Ganciclovir

Minimal Risk HDs in the MAR and label

warfarin (COUMADIN) tablet 1 mg : Dose 1 mg : oral : DAILY



HAZARDOUS DRUG - MINIMAL RISK

Ordered Admin
Amount: 1 tab (1 × 1 mg tab)

Moderate risk HDs
and High Risk HDs
have similar
indications in the
MAR and on the label

9/21/15 1:05 PM

HAZARDOUS DRUG - MINIMAL RISK

Children's Hospital & Medical Center
8200 Dodge Street, Omaha, NE 68114 402.955.5470

DOSE/EDGE, TWO MRN: 4300086
CSN: 40295
MS5-521-521S

ORD#: 221512

warfarin (COUMADIN) tablet 1 mg
1 tab (1 × 1 mg tab)
Route: PO Frequency: QDAY

297750

Verified by: AS
Action: REDISP REP RINT

Tech _____ RPh _____

Moderate Risk HDs in the MAR and label

azaTHIOprine (IMURAN) tablet 50 mg : Dose 50 mg : oral : DAILY : 




Product Instructions:

Take with food.

HAZARDOUS DRUG - MODERATE RISK


Ordered Admin

Amount: 1 tab (1 × 50 mg tab)

9/21/1445	
HAZARDOUS DRUG - MODERATE RISK	
Children's Hospital & Medical Center	
8200 Dodge Street, Omaha, NE 68114	
402.955.5470	
DOSEEDGE, TWO	MRN: 4300088
	CSN: 40295
ORD#: 227949	MS5-521-521S
azaTHIOprine (IMURAN) tablet 50 mg	
1 tab (1 × 50 mg tab)	
Route: PO Frequency: DAILY	
	
Protect from light	Verified by: AS
Action: REDISP REP RNT	
Tech _____ RPh _____	

High Risk HDs in the MAR and label

cidofovir (VISITIDE) 69.75 mg in 0.9% sodium chloride 7.8 mL for injection : Order

Dose 69.75 mg : intravenous : EVERY 48 HOURS : 




Admin Instructions:

Infuse over 1 hour

HAZARDOUS DRUG - HIGH RISK

Ordered Admin
Amount: 69.75 mg

9/3/19 1444	HAZARDOUS DRUG - HIGH RISK
Children's Hospital & Medical Center 8200 Dodge Street, Omaha, NE 68114 402.955.5470	
DOSEEDGE, TWO	
ORD#: 226291	MRN: 4300086
cidofovir (VISITIDE) 69.75 mg in 0.9% sodium chloride	CSN: 40295
7.8 mL for injection	MS5-521-521S
Route: IV	Total Volume: 8.73 mL
Frequency: EVERY 48 HOURS	
Due: 9/3/19 1400	
Tech _____ RPh _____	Verified by: PAH Action: CF REPRINT

Antineoplastic Indicators

DACTINomycin (COSMEGEN) 0.5 mg/mL push injection 0.445 mg



1045 Due

Product Instructions:

Must NOT filter. For IV use ONLY.

HAZARDOUS DRUG - HIGH RISK

ANTINEOPLASTIC

Ordered Admin Amount: 0.445 mg = 0.89 mL of 0.5

10/7/19 1044

HAZARDOUS DRUG - HIGH RISK

Children's Hospital & Medical Center
8200 Dodge Street, Omaha, NE 68114

402.955.5470

DOSEEDGE, TWO

MRN: 4300086

CSN: 40295

ORD#: 236994

MS5-521-521S

DACTINomycin (COSMEGEN) 0.5 mg/mL push
injection 0.445 mg

0.445 mg = 0.89 mL of 0.5 mg/mL

Route: IV Frequency: ONCE



Due: 10/7/19 1045

ANTINEOPLASTIC

Must NOT filter.

Verified by AS
Action: FD REPRINT

Inpatient Signage on Doors

- All patients receiving HDs should have a sign outside their hospital room.
- The signs help to identify that the patient may need different PPE for handling of blood and body fluids.
- Sign in Hubbard Units:

**HAZARDOUS
MEDICATION**



Door Signs in Wiebe Units:

HAZARDOUS MEDICATION PRECAUTIONS Minimal Risk PPE guide			
Hazardous Drug Administration:	Gloves	Chemo Gown	Mask/Goggles or Face Shield
	Single / Wear Double Gloves If risk of splash	If risk of splash	If risk of splash
Managing Blood/Body Fluids:	Gloves	Chemo gown	Mask/Goggles or Face Shield
Cleaning up or handling body fluid	Single	If risk of splash	If risk of splash
Handling Linens	Single	YES	If risk of splash
Blood Specimens	Single	If risk of splash	If risk of splash

HAZARDOUS MEDICATION PRECAUTIONS Moderate / High Risk PPE guide			
Hazardous Drug Administration:	Gloves	Chemo Gown	Mask/Goggles or Face Shield
	Double	YES	If risk of splash
Managing Blood/Body Fluids:	Gloves	Chemo gown	Mask/Goggles or Face Shield
Cleaning up or handling body fluid	Double	YES	If risk of splash
Handling Linens	Double	YES	If risk of splash
Blood Specimens	Single	If risk of splash	If risk of splash

Acknowledgement form



Why do I need to sign an acknowledgement of risk form?

- USP 800 requires in writing that healthcare personnel acknowledge they understand the risks of hazardous medications as it pertains to their job role in the organization.
- Because we are a healthcare facility, any employee could be exposed unknowingly, thus we need to inform all employees of these risks.
 - This form documents that the staff member is aware of the risks with handling HD

References

- USP General Chapter <800> Hazardous Drugs Handling in Healthcare
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings
- APHON Chemotherapy and Biotherapy Curriculum
- BD JCR Improving Safe Handling Practices for Hazardous Drugs
- ONS Safe Handling of Hazardous Drugs
- ASHP The Chapter<800> Answer Book